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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,992	10/22/2001	Joseph M. Patti	P06922US02/BAS	7767

881 7590 10/23/2006

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,992

Applicant(s)

PATTI ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-12,14-21 and 24-32 is/are pending in the application.
4a) Of the above claim(s) 15-17,19-21 and 27-29 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 4, 6-12, 14, 18, 24-26 and 30-32 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed July 31, 2006 has been entered. Claims 1, 4, 6-12, 18, 24, 30 and 32 have been amended. Claims 2-3, 5, 13 and 22-23 have been cancelled. Claims 15-17, 19-21 and 27-29 have been withdrawn. Claims 1, 4, 6-12, 14, 18, 24-26 and 30-32 are under consideration in this office action.
2. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:
 - a) The new matter rejection of claims 2-3, 8 and 18 under 35 U.S.C. 112, first paragraph;
 - b) The rejection of claims 1-4, 6-12, 23, and 30 under 35 U.S.C. 112, second paragraph; and
 - c) The rejection of claims 1-4, 6-12, 18, 23-24 under 35 U.S.C. 101.

Response to Arguments

4. Applicant's arguments filed July 31, 2006 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The objection to the specification is maintained. The objection was on the grounds that the use of the trademarks such as QIAGENTM, SIGMATM, SEPHAROSETM on pages 9,10 and 28 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicants' clarification is required to overcome this objection.

Claim Rejections - 35 USC § 112

6. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, is maintained for reasons already of record. While it is noted that applicants have amended the claims; it is still unclear how the instantly claimed antibody will recognize the same epitopes recognized by an antibody which binds to the *S. aureus* MAP10 protein. It appears that the specification fails to point out what the specific epitope binding regions are for. Therefore without such knowledge, it is unclear how one of ordinary skill in the

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art would be able to determine whether the same epitopes are being recognized by an antibody with binds to the protein having SEQ ID NO:2. Thus, the metes and bounds of the term cannot be ascertained since there is no standard for determining the same epitopes, or antibody recognition abilities. Therefore, the rejection is maintained and applicants' amendments do not overcome the rejection.

Deposit Rejection

7. The deposit rejection of claim 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that the specification lacks complete deposit information for the deposit of hybridoma producing mAb H07. Because it is not clear that cell lines possessing the properties of mAb H07 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of mAb H07, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event. The requirements of this rejection have not been met. Therefore the rejection is maintained.

New Matter Rejection

8. The new matter rejection of claim 8 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

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The rejection was on the grounds that neither the specification nor originally presented claims provides support for an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP10 protein. Applicants' amendments do not obviate the rejection. Applicant still has not pointed to support in the specification for an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP10 protein. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the antibody fragment that recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP10 protein. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity an isolated or purified antibody which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP10 protein having the sequence as set forth in SEQ ID NO: 2 as recited by the amended claim. Therefore, the claim incorporates new matter and is accordingly rejected.

Claim Rejections - 35 USC § 103

9. The rejection of claims 1, 4, 6-12, 14, 18, and 23-24 under 35 U.S.C. 103(a) as being unpatentable over Hook et al., (US Patent 5,648,240) in view of Kohler and Milstein (Nature, 1975. Vol. 256:495-497) is maintained for reasons already of record. The rejection is on the grounds that it would have been *prima facie* obvious at the time of applicants invention to modify the antibodies of Hook et al., ('240) to prepare or

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characterize the antibodies as monoclonal single chain antibody, humanized antibodies or fragments that have the same binding specificity as taught by Hook et al., ('240) since such techniques are well known in the art.

Applicants argue that because the MAP protein of Hook et al., is larger than MAP10, that the antibodies of Hook could not bind the MAP10 protein. However the issue is not the size of the protein, but rather issue is epitope recognition. Therefore the size of MAP as compared to the size of MAP10 is irrelevant. The art sets forth that MAP10 is comprised within MAP. The art sets forth that there are specific binding regions within the MAP protein that will bind antibodies. The art even teaches that the MAP10 protein has these binding regions. Hook et al., teach isolating the Map protein, which has approximately 95% sequence identity to the Map10 protein taught by applicant. Hook et al., teach antibodies that inhibit the binding of *S. aureus*, thus the antibodies of Hook et al., have the same capabilities as those instantly claimed. Moreover, applicants' specification at page 5 states that the Map10 region is the binding region for the whole MAP protein. Therefore, if an antibody binds to the MAP protein, it must also bind to the MAP10 region. Thus, Hook et al., antibodies that bind to the Map protein must also bind to the MAP10 region, and antibodies of Hook et al., thereby meet the claimed limitations.

Applicants' have provided no evidence that the binding regions on the antibody of Hook et al., is different than the antibody of the instant claims. Applicants' have made no argument that the protein of Hook et al., bears different epitopes or binding

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regions as compared to the peptide of the instant application or that an epitope mapping analysis comparing the antibody of the prior art to the antibody of the instant claims differs. Thus, applicants' statements without the provision of scientific evidence that the antibodies of Hook et al., are not capable of binding to the Map10 protein is not found persuasive.

Furthermore, applicants assert the use and abilities drawn to the prevention of bacteremia in mice is a surprising and unexpected property of the instantly claimed antibodies. However, in response to applicant's argument that the Hook et al., reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., being useful in treating infection are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

10. No claims allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
October 13, 2006